TDMS No. 99037 - 05

Test Type: CHRONIC

Species/Strain: RATS/F 344/N

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture

CAS Number: THUJONEMIXAB

F1_R2

C Number: C99037B

Lock Date: 11/20/2006

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

Study Gender: Both

TDMSE Version: 2.1.0

Date Report Requested: 05/28/2009

Time Report Requested: 08:41:38 First Dose M/F: 06/09/03 / 06/09/03

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FISCHER 344 RATS MALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Disposition Summary				
Animals Initially in Study Early Deaths	50	50	50	50
Dosing Accident	2		1	
Moribund Sacrifice	14	21	13	1
Natural Death	7	4	19	49
Survivors Natural Death	1			
Terminal Sacrifice	1 26	25	17	
Animals Examined Microscopically	50 50	50	50	50
. ,				
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Hemorrhage	1 [2.0]			
Hyperkeratosis				1 [2.0]
Inflammation, Acute	2 [3.0]			
Perforation	1	(40)	(40)	(00)
Intestine Large, Cecum	(48)	(48)	(40)	(39)
Edema Inflammation, Acute	1 [4.0]			
Necrosis, Lymphoid	1 [2.0]			1 [1.0]
Intestine Large, Colon	(44)	(47)	(33)	(15)
Edema	2 [3.0]	1 [2.0]	1 [2.0]	(13)
Hemorrhage	- [0.0]	. [=.0]	1 [1.0]	
Necrosis			1 [2.0]	
Intestine Large, Rectum	(46)	(48)	(41)	(42)
Inflammation, Chronic				1 [2.0]
Intestine Small, Duodenum	(48)	(48)	(37)	(33)
Necrosis, Lymphoid		`	(a =)	1 [1.0]
Intestine Small, Ileum	(43)	(47)	(30)	(16)
Inflammation, Acute	4 [0 0]		1 [1.0]	1 [1.0]
Inflammation, Chronic Active Necrosis	1 [2.0] 1 [1.0]	1 [1.0]		
Intestine Small, Jejunum	(43)	(47)	(33)	(25)
Liver	(50)	(50)	(50)	(50)
Basophilic Focus	29	26	25	4

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FISCHER 344 RATS MALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG	
Clear Cell Focus	19	23	11	4	
Degeneration, Cystic	13 [1.4]	7 [1.4]	4 [1.5]	2 [1.0]	
Eosinophilic Focus	6	4	4	1	
Fibrosis				1 [1.0]	
Hematopoietic Cell Proliferation		1 [1.0]			
Hepatodiaphragmatic Nodule	8	3	5	3	
Infiltration Cellular, Mixed Cell	21 [1.1]	22 [1.3]	18 [1.1]	9 [1.1]	
Mixed Cell Focus	3	6	3	2	
Necrosis, Focal		1 [1.0]		3 [1.7]	
Thrombosis		1			
Bile Duct, Hyperplasia	41 [2.3]	45 [2.6]	40 [2.4]	20 [2.1]	
Centrilobular, Necrosis	1	1 [4.0]	1 [4.0]	5 [2.8]	
Hepatocyte, Vacuolization Cytoplasmic	7 [2.3]	10 [2.6]	4 [3.0]	1 [1.0]	
Hepatocyte, Vacuolization Cytoplasmic,	,	2 [1.0]	1 [1.0]	1 [1.0]	
Focal		,	,	1 -1	
Kupffer Cell, Pigmentation		4 [1.8]			
Mesentery	(11)	(10)	(11)	(4)	
Accessory Spleen	(/	`1 '	`1 ´	2	
Hemorrhage			1 [4.0]	1 [4.0]	
Fat, Necrosis	10 [2.4]	9 [1.9]	8 [2.1]	1 [2.0]	
Oral Mucosa	(0)	(1)	(0)	(1)	
Pancreas	(50)	(50)	(50)	(50)	
Atrophy	29 [1.7]	35 [1.9]	30 [1.8]	18 [1.8]	
Cyst	21	25	15	6	
Hemorrhage				1 [2.0]	
Necrosis		1 [3.0]		1 [1.0]	
Acinus, Hyperplasia, Focal	8 [1.8]	1 [1.0]	6 [2.5]	. []	
Salivary Glands	(50)	(50)	(50)	(50)	
Atrophy	7 [1.1]	4 [1.8]	9 [1.3]	(/	
Hyperplasia	. []	. [0]	0 [0]	1 [1.0]	
Inflammation, Acute	1 [1.0]		1 [2.0]	. []	
Inflammation, Chronic	. []	2 [1.5]	. []		
Necrosis		2[]		1 [3.0]	
Duct, Hyperplasia	1 [1.0]			. [0.0]	
Stomach, Forestomach	(50)	(50)	(50)	(49)	
Edema	2 [3.0]	4 [2.3]	1 [4.0]	(10)	
Erosion	1 [1.0]	. [2.0]	. [•]		
Inflammation, Chronic Active	· [· · •]		1 [2.0]		
Stromal Hyperplasia			۰ رح.۰۰	1 [3.0]	
Ottornar riyporpiasia	1 [4.0]	3 [2.7]	2 [4.0]	راه. در	

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FISCHER 344 RATS MALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG	
Epithelium, Hyperplasia	9 [2.3]	12 [2.2]	13 [1.7]	3 [2.0]	
Stomach, Glandular	(50)	(50)	(49)	(48)	
Cyst Edema		1 2 [2.0]	1 [3.0]		
Erosion	3 [1.0]	2 [2.0] 6 [1.7]	6 [2.0]	1 [2.0]	
Hemorrhage	0 [1.0]	0[1.7]	0 [2.0]	2 [1.0]	
Inflammation		1 [1.0]		-[]	
Necrosis, Lymphoid				2 [2.0]	
Ulcer	2 [3.0]	5 [2.6]	2 [3.0]		
CARDIOVASCULAR SYSTEM					
Heart	(50)	(50)	(50)	(50)	
Cardiomyopathy	44 [1.4]	41 [1.4]	47 [1.4]	45 [1.3]	
Hemorrhage	[]	[]	[]	2 [2.0]	
Hypertrophy		1 [2.0]			
Thrombosis	3	4	2		
Epicardium, Inflammation		1 [1.0]			
ENDOCRINE SYSTEM					
Adrenal Cortex	(50)	(50)	(49)	(50)	
Accessory Adrenal Cortical Nodule	21 [1.3]	19 [1.2]	21 [1.5]	4 [1.0]	
Degeneration, Fatty	26 [1.5]	28 [1.7]	31 [1.5]	34 [1.2]	
Hematopoietic Cell Proliferation	2 [1.0]	2 [1.5]			
Hyperplasia, Focal	17 [1.4]	11 [1.4]	9 [1.8]	4 [1.3]	
Hypertrophy, Focal	6 [2.0]	2 [1.5]	4 [0.0]	0.14.51	
Necrosis Bilateral, Necrosis	1 [1.0]	3 [1.3]	1 [2.0]	2 [1.5]	
Capsule, Hyperplasia	1 [4.0] 1 [2.0]		1 [1.0]		
Adrenal Medulla	(50)	(50)	(49)	(49)	
Hyperplasia	18 [1.8]	25 [1.9]	13 [2.2]	1 [3.0]	
Infiltration Cellular, Lymphocyte	.0[0]	2 [1.0]	. 0 [=.=]	, [0.0]	
Islets, Pancreatic	(50)	(50)	(50)	(50)	
Hyperplasia	3 [1.3]		3 [3.0]	1 [3.0]	
Parathyroid Gland	(48)	(49)	(47)	(49)	
Hyperplasia, Focal		1 [2.0]	1 [2.0]		
Pituitary Gland	(50)	(50)	(50)	(47)	
Infiltration Cellular, Histiocyte			1 [4.0]		

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ISCHER 344 RATS MALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG	
Pigmentation	7 [1.4]	7 [1.9]	10 [2.0]	1 [1.0]	
Pars Distalis, Angiectasis	2 [2.0]	2 [1.5]	1 [2.0]	3 [1.7]	
Pars Distalis, Cyst	6	3	4	2	
Pars Distalis, Hemorrhage				2 [2.5]	
Pars Distalis, Hyperplasia, Focal	16 [1.9]	13 [1.8]	3 [1.3]	5 [2.6]	
Pars Distalis, Necrosis				1 [4.0]	
Pars Distalis, Pars Intermedia, Necrosis		4 [0 5]	4 [4 0]	1 [4.0]	
Pars Intermedia, Angiectasis	4	4 [2.5]	1 [1.0]	1 [1.0]	
Pars Intermedia, Cyst Pars Intermedia, Hyperplasia, Focal	4	1 [1 0]	1		
Rathke's Cleft, Cyst	2 [1.5]	1 [1.0] 2			
hyroid Gland	(46)	(48)	(42)	(45)	
Degeneration, Cystic	7 [1.1]	6 [1.0]	4 [1.0]	7 [1.3]	
Ultimobranchial Cyst	2 [1.5]	2 [1.0]	1 [1.0]	2 [1.5]	
C-cell, Hyperplasia	2 [2.5]	7 [2.4]	2 [3.0]	_[]	
Follicular Cell, Hyperplasia, Focal		2 [2.5]	1 [2.0]	1 [4.0]	
IERAL BODY SYSTEM					
issue NOS	(1)	(1)	(2)	(0)	
IITAL SYSTEM					
pididymis	(50)	(50)	(50)	(50)	
Granuloma Sperm		1 [2.0]			
enis	(0)	(1)	(0)	(1)	
Inflammation, Acute	(40)	1 [2.0]	(=0)	(50)	
reputial Gland	(49)	(49)	(50)	(50)	
Cyst Hyperplasia	1 2 [2.5]		1 [3.0]		
Inflammation, Chronic	2 [2.5] 13 [2.5]	19 [2.1]	1 [3.0] 18 [2.2]	5 [2.2]	
Necrosis	13 [2.0]	19 [2.1] 1 [4.0]	10 [2.2]	5 [2.2]	
rostate	(50)	(50)	(50)	(50)	
Fibrosis	1 [2.0]	(00)	1 [2.0]	(00)	
Inflammation, Chronic	32 [1.8]	20 [2.1]	23 [2.3]	9 [2.0]	
Mineralization	r -1	1 [2.0]	1		
Necrosis		1 [3.0]	1 [4.0]		
Epithelium, Hyperplasia	23 [1.3]	17 [1.6]	18 [1.3]	4 [1.5]	
eminal Vesicle	(50)	(50)	(50)	(50)	

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FISCHER 344 RATS MALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Hyperplasia		1 [2.0]		
Infiltration Cellular		4 [4 0]	4 [4 0]	1 [4.0]
Inflammation, Acute Inflammation, Chronic		1 [4.0] 1 [3.0]	1 [1.0]	1 [1.0]
Necrosis		1 [3.0]		
Testes	(50)	(50)	(50)	(50)
Germinal Epithelium, Atrophy	5 [2.2]	2 [3.5]	3 [2.7]	4 [3.5]
Interstitial Cell, Hyperplasia	9 [1.3]	5 [1.6]	6 [1.7]	13 [1.7]
EMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Hyperplasia	7 [2.6]	7 [2.7]	12 [2.3]	4 [1.8]
Myelofibrosis Necrosis	5 [1.6]	4 [2.0]		
Thrombosis		1 [2.0] 1		
Lymph Node	(12)	(14)	(12)	(5)
Mediastinal, Ectasia	1 [3.0]	()	(/	(-)
Mediastinal, Hemorrhage	2 [3.0]			1 [1.0]
Mediastinal, Hyperplasia, Lymphoid	1 [2.0]	1 [4.0]	3 [3.0]	1 [2.0]
Mediastinal, Pigmentation Pancreatic, Hemorrhage	1 [1.0]		1 [3.0]	1 [4.0]
Pancreatic, Hernormage Pancreatic, Hyperplasia, Lymphoid	1 [1.0]	1 [2.0]		3 [2.0]
Pancreatic, Necrosis, Lymphoid		1 [2.0]		1 [1.0]
Pancreatic, Pigmentation	1 [1.0]			1 [2.0]
Lymph Node, Mandibular	(2)	(0)	(0)	(3)
Congestion				1 [2.0]
Hyperplasia, Lymphoid Lymph Node, Mesenteric	(50)	(49)	(50)	1 [2.0] (50)
Ectasia	1 [3.0]	1 [4.0]	1 [2.0]	(30)
Hemorrhage	4 [1.3]	2 [1.0]	10 [1.6]	10 [1.3]
Hyperplasia, Lymphoid	1 [2.0]	3 [2.3]	7 [2.1]	7 [2.3]
Necrosis	(==)	1 [2.0]	2 [2.0]	1 [2.0]
Spleen Accessory Spleen	(50)	(50)	(49)	(48)
Accessory Spieen Angiectasis	1 [4.0]			I
Fibrosis	2 [2.0]	3 [3.0]	1 [2.0]	
Hematopoietic Cell Proliferation	6 [2.2]	7 [2.9]	1 [4.0]	1 [2.0]
Hemorrhage	1 [3.0]	-	-	-

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FISCHER 344 RATS MALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG	
Infarct	1 [3.0]	1 [4.0]	1 [3.0]		
Necrosis		1 [2.0]	2 [3.0]	3 [1.0]	
Pigmentation	19 [2.0]	24 [1.5]	30 [2.1]	46 [2.2]	
Lymphoid Follicle, Atrophy		1 [1.0]	2 [2.0]	1 [2.0]	
Lymphoid Follicle, Hyperplasia	10 [1.6]	12 [1.6]	8 [1.6]	3 [1.7]	
Thymus	(44)	(45)	(45)	(47)	
Cyst		1	4 [4 0]		
Ectopic Parathyroid Gland		4 [0 0]	1 [1.0]		
Fibrosis		1 [3.0]			
NTEGUMENTARY SYSTEM					
Mammary Gland	(50)	(50)	(50)	(50)	
Angiectasis		1 [3.0]			
Cyst	3	1	2	2	
Fibrosis	1 [3.0]				
Hyperplasia	22 [2.0]	26 [1.6]	34 [1.7]	29 [1.4]	
Skin	(50)	(50)	(50)	(50)	
Cyst Epithelial Inclusion		2	4	4 70 01	
Edema				1 [2.0]	
Hemorrhage	4 [0.0]	0.00	<i>E</i> [O O]	1 [2.0]	
Hyperkeratosis	1 [2.0]	3 [3.0]	5 [2.8]	1 [2.0]	
Inflammation, Granulomatous Inflammation, Chronic	1 [4.0]		4 [2.3]	3 [1.7]	
Mineralization			4 [2.3] 1 [2.0]	3[1.7]	
Necrosis			1 [3.0]		
Ulcer			1 [0.0]	2 [3.5]	
Ulcer, Multiple				1 [3.0]	
Epidermis, Hyperkeratosis	1 [4.0]			. [6.0]	
Epidermis, Hyperplasia	. []	1 [2.0]	3 [2.7]		
Epidermis, Hyperplasia, Focal	1 [3.0]				
Hair Follicle, Cyst		1			
Subcutaneous Tissue, Fibrosis			1 [1.0]		
MUSCULOSKELETAL SYSTEM					
Bone	(50)	(50)	(50)	(50)	
Femur, Osteopetrosis	ζ/	2 [2.0]	2 [2.0]	(/	
Skeletal Muscle	(2)	(4)	(2)	(0)	
	` '	` /	` /	` '	

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FISCHER 344 RATS MALE Fibrosis 2 [3.5]	
Brain	
Brain (50) (50) (50) (50) (50) Compression 9 4 12 1 Mineralization 1 [2.0] 1 [2.0] 1 [2.0] Necrosis 2 [2.5] 2 [2.5] RESPIRATORY SYSTEM Lung (50) (50) (50) (50) Lung (50) (50) 33 [1.1] 18 [1.0] Inflating the properties of the properti	
Compression 9 4 12 12 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
Mineralization 1 [2.0] 1 [2.0] 2 [2.5]	
Necrosis 2 [2.5]	
Lung	
Lung (50) (50) (50) (50) (50) (50) (50) (50)	
Infiltration Cellular, Histiocyte 31 [1.1] 43 [1.0] 33 [1.1] 18 [1.0] Inflammation, Chronic 1 [1.0] 6 [1.3] 2 [1.5] 4 [1.5] 4 [1.5] Metaplasia, Osseous 2 [1.0] 5 [1.4] 6 [1.2] 2 [1.5] Thrombosis 1 1 [1.7] 17 [1.2] 19 [1.5] 3 [2.0] Nose (50) (50) (50) (50) (50) (50) (50) (50)	
Infiltration Cellular, Histiocyte 31 [1.1] 43 [1.0] 33 [1.1] 18 [1.0] Inflammation, Chronic 1 [1.0] 6 [1.3] 2 [1.5] 4 [1.5] 4 [1.5] Metaplasia, Osseous 2 [1.0] 5 [1.4] 6 [1.2] 2 [1.5] Thrombosis 1 1 [1.7] 17 [1.2] 19 [1.5] 3 [2.0] Nose (50) (50) (50) (50) (50) (50) (50) (50)	
Inflammation, Chronic I [1.0] Metaplasia, Osseous 2 [1.0] Alveolar Epithelium, Hyperplasia Alveolar Epithelium, Hyperplasia 11 [1.7] Nose (50) Congestion Foreign Body Inflammation, Chronic Infla	
Metaplasia, Osseous 2 [1.0] 5 [1.4] 6 [1.2] 2 [1.5] Thrombosis 1 Alveolar Epithelium, Hyperplasia 11 [1.7] 17 [1.2] 19 [1.5] 3 [2.0] Nose (50) (50) (50) (50) Congestion 1 [3.0] Foreign Body 11 [1.6] 8 [1.8] 9 [1.4] 1 [2.0] Inflammation, Chronic 13 [1.6] 15 [1.6] 13 [1.7] 2 [1.5] Goblet Cell, Hyperplasia 2 [1.5] 1 [2.0] 3 [1.7] 1 [2.0] Respiratory Epithelium, Hyperplasia 13 [1.4] 7 [1.6] 10 [1.6] 1 [1.0] Trachea (50) (50) (50) (50) Inflammation, Acute 1 [3.0] SPECIAL SENSES SYSTEM Eye (49) (50) (50) (46) (48)	
Thrombosis Alveolar Epithelium, Hyperplasia 11 [1.7] 17 [1.2] 19 [1.5] 3 [2.0] Nose (50) (50) (50) (50) Congestion Foreign Body 11 [1.6] 8 [1.8] 9 [1.4] 1 [2.0] Inflammation, Chronic 13 [1.6] 15 [1.6] 13 [1.7] 2 [1.5] Goblet Cell, Hyperplasia 2 [1.5] 1 [2.0] Respiratory Epithelium, Hyperplasia 13 [1.4] 7 [1.6] 10 [1.6] 11 [1.0] Trachea (50) Inflammation, Acute 1 [3.0] SPECIAL SENSES SYSTEM Eye (49) (50) (50) (46) (48)	
Alveolar Epithelium, Hyperplasia 11 [1.7] 17 [1.2] 19 [1.5] 3 [2.0] Nose (50) Congestion Foreign Body Inflammation, Chronic Goblet Cell, Hyperplasia Respiratory Epithelium, Hyperplasia Trachea (50)	
Nose (50) (50) (50) (50) (50) (50) (50) (50)	
Congestion Foreign Body Inflammation, Chronic Inflammation, Inflammation Inflam	
Foreign Body 11 [1.6] 8 [1.8] 9 [1.4] 1 [2.0] Inflammation, Chronic 13 [1.6] 15 [1.6] 13 [1.7] 2 [1.5] Goblet Cell, Hyperplasia 2 [1.5] 1 [2.0] 3 [1.7] 1 [2.0] Respiratory Epithelium, Hyperplasia 13 [1.4] 7 [1.6] 10 [1.6] 1 [1.0] Trachea (50) (50) (50) (50) (50) (50) SPECIAL SENSES SYSTEM Eye (49) (50) (46) (48)	
Inflammation, Chronic 13 [1.6] 15 [1.6] 13 [1.7] 2 [1.5] Goblet Cell, Hyperplasia 2 [1.5] 1 [2.0] 3 [1.7] 1 [2.0] Respiratory Epithelium, Hyperplasia 13 [1.4] 7 [1.6] 10 [1.6] 1 [1.0] Trachea (50) (50) (50) (50) (50) Inflammation, Acute 1 [3.0] 1 [3.0] (50) (46) (48)	
Goblet Cell, Hyperplasia 2 [1.5] 1 [2.0] 3 [1.7] 1 [2.0] Respiratory Epithelium, Hyperplasia 13 [1.4] 7 [1.6] 10 [1.6] 1 [1.0] Trachea (50) (50) (50) (50) Inflammation, Acute 1 [3.0] SPECIAL SENSES SYSTEM Eye (49) (50) (46) (48)	
Respiratory Epithelium, Hyperplasia 13 [1.4] 7 [1.6] 10 [1.6] 1 [1.0] Trachea (50) (50) (50) (50) Inflammation, Acute 1 [3.0] SPECIAL SENSES SYSTEM Eye (49) (50) (46) (48)	
Trachea (50) (50) (50) (50) (50) Inflammation, Acute 1 [3.0] SPECIAL SENSES SYSTEM Eye (49) (50) (46) (48)	
Inflammation, Acute 1 [3.0] SPECIAL SENSES SYSTEM Eye (49) (50) (46) (48)	
Eye (49) (50) (46) (48)	
Eye (49) (50) (46) (48)	
()	
Cataract 6 [1.3] 9 [1.7] 10 [1.3] 2 [2.5]	
Developmental Malformation 1 [3.0]	
Edema 1 [3.0] 1 [2.0]	
Hemorrhage 1 [3.0]	
Inflammation, Chronic 2 [2.5]	
Bilateral, Cataract 1 [4.0] 2 [1.5] 2 [1.5]	
Retina, Degeneration 1 [4.0] 2 [3.0]	
Harderian Gland (50) (50) (50) (50)	
Hyperplasia, Focal 1 [3.0] 1 [1.0] 1 [1.0]	

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

TDMS No. 99037 - 05

Test Type: CHRONIC

Species/Strain: RATS/F 344/N

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture

CAS Number: THUJONEMIXAB

Date Report Requested: 05/28/2009

Time Report Requested: 08:41:38 First Dose M/F: 06/09/03 / 06/09/03

Lab: SRI

FISCHER 344 RATS MALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Inflammation, Chronic Pigmentation	3 [1.0]	4 [1.5] 1 [4.0]	4 [1.0]	5 [1.2]
Zymbal's Gland	(0)	(1)	(1)	(0)
URINARY SYSTEM				
Kidney Casts Granular	(48)	(48)	(44)	(49)
Casts Protein	1 [3.0] 18 [1.1]	30 [1.5]	22 [1.5]	11 [1.6]
Cyst Hydronephrosis Infarct	1 1 [2.0] 3 [2.3]	3 1 [3.0] 1 [3.0]		
Inflammation, Suppurative Mineralization	17 [1.0]	2 [2.5] 33 [1.4]	41 [1.6]	1 [1.0] 38 [1.5]
Nephropathy	45 [1.5]	44 [1.7]	41 [1.7]	46 [1.3]
Artery, Thrombosis Papilla, Necrosis Renal Tubule, Accumulation, Hyaline	1 1 [3.0] 1 [4.0]			
Droplet Renal Tubule, Necrosis				2 [2.5]
Transitional Epithelium, Hyperplasia Urinary Bladder	(50)	1 [1.0] (50)	4 [1.3] (49)	2 [2.5] (50)
Atrophy Hemorrhage		1 [3.0]		1 [1.0]
Inflammation, Acute		1 [4.0]		
Inflammation, Chronic Necrosis		1 [2.0] 1 [4.0]		1 [1.0]
Transitional Epithelium, Hyperplasia		1 [1.0]		1 [2.0]

*** END OF MALE ***

a - Number of animals examined microscopically at site and number of animals with lesion

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Species/Strain: RATS/F 344/N

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture

CAS Number: THUJONEMIXAB

Time Report Requested: 08:41:38 First Dose M/F: 06/09/03 / 06/09/03

Date Report Requested: 05/28/2009

FISCHER 344 RATS FEMALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG	
Disposition Summary					
Animals Initially in Study	50	50	50	50	
Early Deaths					
Moribund Sacrifice	6	9	10	5	
Natural Death	9	8	21	45	
Survivors	05	00	40		
Terminal Sacrifice Animals Examined Microscopically	35 50	33 50	19 50	50	
Animais Examined Microscopically	30	50	50	50	
ALIMENTARY SYSTEM					
Esophagus	(50)	(50)	(50)	(50)	
Diverticulum	1	,			
Intestine Large, Cecum	(41)	(44)	(39)	(47)	
Hemorrhage		1 [1.0]			
Intestine Large, Colon	(41)	(43)	(33)	(25)	
Intestine Large, Rectum	(46)	(45)	(41)	(47)	
Hemorrhage	(44)	(45)	(40)	1 [3.0]	
Intestine Small, Duodenum Necrosis	(44)	(45)	(40) 1 [1.0]	(47)	
Necrosis, Lymphoid			1 [1.0]	1 [1.0]	
Intestine Small, Jejunum	(41)	(42)	(33)	(31)	
Necrosis, Lymphoid	(' ' /	('-/	(00)	1 [1.0]	
Liver	(50)	(50)	(49)	(50)	
Angiectasis	1 [2.0]		1 [2.0]		
Basophilic Focus	46	46	40	12	
Clear Cell Focus	17	21	11		
Eosinophilic Focus	8	2	2		
Hematopoietic Cell Proliferation	1 [1.0]	1 [1.0]	4 [1.0]		
Hepatodiaphragmatic Nodule	5	8	6	4	
Infiltration Cellular, Histiocyte Infiltration Cellular, Mixed Cell	30 [1.1]	20 [4 2]	32 [1.1]	1 [2.0] 19 [1.2]	
Inflammation, Chronic	30 [1.1]	30 [1.3]	32 [1.1] 1 [1.0]	19[1.2]	
Mixed Cell Focus	10	4	4		
Necrosis, Focal	1 [1.0]	1 [1.0]	5 [1.4]	4 [1.5]	
Artery, Inflammation	[]	1 [3.0]	1 [3.0]	r1	
Bile Duct, Hyperplasia	4 [1.5]	2 [1.5]	7 [2.0]		

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Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture

CAS Number: THUJONEMIXAB

Lab: SRI

Date Report Requested: 05/28/2009

Time Report Requested: 08:41:38

First Dose M/F: 06/09/03 / 06/09/03

Species/Strain: RATS/F 344/N

ISCHER 344 RATS FEMALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG	
Capsule, Fibrosis	1 [3.0]				
Centrilobular, Necrosis			3 [3.3]		
Hepatocyte, Vacuolization Cytoplasmic	5 [3.0]	4 [2.0]	3 [2.7]		
Kupffer Cell, Pigmentation		1 [2.0]	1 [1.0]		
Mesentery	(13)	(11)	(9)	(2)	
Accessory Spleen	(- /	`1 ′	(9) 2	1 [2.0]	
Necrosis				1 [1.0]	
Fat, Necrosis	13 [2.2]	10 [2.3]	8 [2.1]	1 [3.0]	
Oral Mucosa	(0)	(2)	(0)	(0)	
Inflammation, Chronic Active	(0)	1 [4.0]	(0)	(5)	
Pancreas	(49)	(49)	(50)	(50)	
Atrophy	25 [1.4]	24 [1.3]	23 [1.2]	5 [1.2]	
Cyst	14	11	9	1	
Acinus, Hyperplasia, Focal	2 [1.5]	1 [2.0]	2 [2.5]	·	
Salivary Glands	(50)	(50)	(50)	(50)	
Atrophy	9 [1.1]	10 [1.1]	5 [1.0]	2 [1.0]	
Hyperplasia	0 []		0 [0]	1 [1.0]	
Inflammation, Chronic		1 [2.0]		. [0]	
Mineralization		2 [1.0]		1 [1.0]	
Necrosis		2[0]		1 [3.0]	
Vacuolization Cytoplasmic		1 [3.0]		1 [2.0]	
Stomach, Forestomach	(50)	(50)	(50)	(50)	
Edema	2 [2.0]	1 [2.0]	(00)	(00)	
Inflammation, Chronic Active	2 [2.0]	1 [2.0]	1 [1.0]		
Ulcer	1 [4.0]	2 [2.5]	. [1.0]		
Epithelium, Hyperplasia	7 [1.4]	8 [1.8]	2 [2.0]		
Epithelium, Hyperplasia, Atypical	, [11]	o [1.0]	1 [2.0]		
Stomach, Glandular	(48)	(47)	(48)	(50)	
Cyst	(.0)	1	(.0)	(55)	
Edema	1 [3.0]	·			
Erosion	1 [1.0]	1 [3.0]	1 [2.0]	3 [2.0]	
Ulcer	1 [4.0]	. [0.0]	3 [2.3]	1 [2.0]	
ongue	(1)	(3)	(0)	(0)	
Hyperplasia	1 [2.0]	2 [2.5]	(=)	(5)	
Ulcer	. [=.0]	1 [4.0]			
ooth	(0)	(1)	(0)	(0)	
Degeneration	(0)	1 [2.0]	(0)	(0)	

CARDIOVASCULAR SYSTEM

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: RATS/F 344/N

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture

CAS Number: THUJONEMIXAB

Time Report Requested: 08:41:38 First Dose M/F: 06/09/03 / 06/09/03

Date Report Requested: 05/28/2009

FISCHER 344 RATS FEMALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	40 [1.1]	30 [1.1]	30 [1.2]	8 [1.0]
Hemorrhage				1 [2.0]
Artery, Necrosis				1 [2.0]
ENDOCRINE SYSTEM				
Adrenal Cortex	(47)	(49)	(46)	(50)
Accessory Adrenal Cortical Nodule	7 [1.4]	12 [1.6]	13 [1.3]	9 [1.3]
Degeneration, Fatty	23 [1.9]	18 [1.8]	19 [1.7]	9 [1.3]
Hematopoietic Cell Proliferation	1 [1.0]	2 [1.5]	4 [1.0]	
Hemorrhage _			1 [3.0]	3 [2.7]
Hyperplasia, Focal	22 [1.5]	14 [1.7]	9 [1.6]	1 [1.0]
Hypertrophy, Focal	7 [1.7]	6 [1.3]	2 [1.0]	1 [2.0]
Inflammation, Acute	0 [0 5]	4 [4 0]	0 [0 7]	1 [2.0]
Necrosis	2 [2.5]	1 [1.0]	6 [2.7]	4 [2.5]
Adrenal Medulla	(48)	(50)	(48)	(50)
Angiectasis Hyperplasia	7 [1.1]	5 [1.8]	3 [2.0]	1 [2.0]
Infiltration Cellular, Lymphoid	7 [1.1]	1 [1.0]	3 [2.0]	
Islets, Pancreatic	(49)	(49)	(50)	(50)
Hyperplasia	1 [1.0]	(49)	1 [4.0]	(30)
Pituitary Gland	(50)	(49)	(49)	(45)
Infiltration Cellular, Histiocyte	(00)	(10)	(10)	8 [1.6]
Pigmentation	5 [1.6]	5 [1.4]	9 [1.4]	8 [1.4]
Pars Distalis, Angiectasis	9 [2.2]	4 [2.0]	5 [2.2]	2 [1.0]
Pars Distalis, Cyst	18	20	18	8
Pars Distalis, Hyperplasia, Focal	5 [1.6]	13 [2.0]	6 [2.5]	1 [2.0]
Pars Intermedia, Angiectasis	2 [3.5]			
Pars Intermedia, Cyst	1	2	2	2
Pars Intermedia, Hyperplasia	1 [1.0]			
Rathke's Cleft, Cyst			3	14
Thyroid Gland	(42)	(46)	(44)	(50)
Degeneration, Cystic	1 [1.0]	2 [1.0]	5 [1.6]	
Ectopic Thymus	0.14.01	4.54.03	0.14.03	1 [2.0]
Ultimobranchial Cyst	2 [1.0]	1 [1.0]	3 [1.3]	2 [2.0]
C-cell, Hyperplasia	1 [1.0]	11 [2.4]	2 [1.5]	
Follicular Cell, Hyperplasia, Focal		1 [2.0]	1 [1.0]	

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Species/Strain: RATS/F 344/N

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture

CAS Number: THUJONEMIXAB

Time Report Requested: 08:41:38 First Dose M/F: 06/09/03 / 06/09/03

Date Report Requested: 05/28/2009

FISCHER 344 RATS FEMALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
GENERAL BODY SYSTEM				
Tissue NOS Fat, Mediastinum, Necrosis	(1) 1 [2.0]	(1)	(0)	(0)
GENITAL SYSTEM				
Clitoral Gland Cyst	(50) 2	(50)	(50) 1	(50)
Hyperplasia	9 [2.2]	7 [1.9]	11 [2.7]	4 [0.0]
Infiltration Cellular, Lymphocyte Inflammation, Chronic Ovary Cyst	(50) 3	(50) 6	1 [2.0] (50) 2	1 [2.0] 1 [1.0] (50) 1
Bilateral, Cyst Uterus	(50)	(50)	1 (49)	(50)
Cyst Hyperplasia, Cystic	1 22 [2.2]	17 [1.8]	19 [2.2]	9 [2.2]
Cervix, Cyst Fat, Necrosis Vagina	(2)	1 [2.0] (2)	1 (1)	(0)
HEMATOPOIETIC SYSTEM				
Bone Marrow Hyperplasia	(50) 4 [3.3]	(50) 6 [3.5]	(50) 6 [3.5]	(50)
Infiltration Cellular, Histiocyte Myelofibrosis	1 [4.0]	1 [1.0] 1 [3.0]	2 [1.0]	4 [1.8]
Necrosis Lymph Node	(7)	(8)	(6)	1 [2.0] (7)
Deep Cervical, Hyperplasia Deep Cervical, Pigmentation	()	1 [3.0] 1 [3.0]	\ -1	. ,
Iliac, Hemorrhage Iliac, Hyperplasia, Lymphoid Iliac, Pigmentation		. [6.6]		1 [2.0] 1 [2.0] 1 [2.0]
Mediastinal, Hemorrhage Mediastinal, Hyperplasia, Lymphoid		2 [3.0] 6 [2.7]	2 [2.0] 3 [2.0]	2 [4.0] 2 [2.5]
Mediastinal, Pigmentation Pancreatic, Hemorrhage		5 [2.2] 1 [2.0]	1 [2.0] 2 [3.0]	1 [2.0] 1 [3.0]

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Species/Strain: RATS/F 344/N

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture

CAS Number: THUJONEMIXAB

Time Report Requested: 08:41:38 First Dose M/F: 06/09/03 / 06/09/03

Date Report Requested: 05/28/2009

FISCHER 344 RATS FEMALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG	
Pancreatic, Hyperplasia, Lymphoid			1 [2.0]	4 [2.3]	
Pancreatic, Pigmentation		1 [3.0]	1 [2.0]	1 [2.0]	
Lymph Node, Mandibular	(1)	(4)	(1)	(4)	
Hyperplasia, Lymphoid	1 [1.0]	4 [1.5]	,	2 <u>[</u> 2.5]	
Pigmentation	• •	1 [2.0]			
Lymph Node, Mesenteric	(50)	(50)	(48)	(50)	
Atrophy	1 [2.0]	1 [3.0]	,	` ,	
Ectasia	1 [3.0]				
Hemorrhage	8 [1.6]	9 [1.7]	6 [1.7]	3 [1.7]	
Hyperplasia, Lymphoid	35 [1.5]	42 [1.5]	37 [1.6]	43 [2.3]	
Necrosis		,	1 [1.0]	1 [2.0]	
Pigmentation			1 [2.0]	,	
Spleen	(48)	(49)	(48)	(50)	
Ectopic Spleen, Multiple	,	`1 ´	,	,	
Fibrosis	1 [3.0]				
Hematopoietic Cell Proliferation	21 [1.4]	31 [1.6]	21 [2.0]		
Hemorrhage	1 [3.0]				
Inflammation		1 [3.0]			
Necrosis		1 [4.0]	3 [2.3]	4 [1.8]	
Pigmentation	39 [2.7]	40 [2.6]	39 [2.9]	45 [2.4]	
Lymphoid Follicle, Atrophy	2 [1.5]	3 [1.7]	2 [2.5]	2 [2.0]	
Lymphoid Follicle, Hyperplasia	3 [1.3]	3 [1.0]	2 [1.0]	8 [2.0]	
Lymphoid Follicle, Hyperplasia, Focal	- 1 - 1		1 [3.0]		
Thymus	(48)	(45)	(50)	(50)	
Cyst	\ /	`2 ′	,	,	
Ectopic Parathyroid Gland	1 [2.0]				
Necrosis			1 [1.0]	3 [1.7]	
TEGUMENTARY SYSTEM					
Mammary Gland	(50)	(50)	(50)	(50)	
Cyst	, ,	`1 ′	`1´	,	
Fibrosis	1 [4.0]				
Hyperplasia	37 [2.4]	42 [2.5]	32 [2.1]		
Hyperplasia, Focal	4 [1.5]	1 [1.0]			
Malformation			1		
Duct, Ectasia	5 [2.6]	4 [3.3]	4 [2.3]		
Skin	(50)	(50)	(50)	(50)	
Cyst Epithelial Inclusion	2	(/	1	ζ/	

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Species/Strain: RATS/F 344/N

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture

CAS Number: THUJONEMIXAB

Time Report Requested: 08:41:38 First Dose M/F: 06/09/03 / 06/09/03

Date Report Requested: 05/28/2009

FISCHER 344 RATS FEMALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG	
Hyperkeratosis	1 [4.0]	1 [2.0]	1 [2.0]		
Inflammation, Chronic	1 [1.0]	4 [4 0]			
Ulcer Epidermis, Hyperplasia	2 [2.0]	1 [4.0] 1 [2.0]			
Subcutaneous Tissue, Fibrosis	1 [3.0]	. [2.0]			
MUSCULOSKELETAL SYSTEM					
Bone	(50)	(50)	(50)	(50)	
Femur, Osteopetrosis	1 [1.0]	1 [2.0]			
Skeletal Muscle	(0)	(0)	(1)	(0)	
NERVOUS SYSTEM					
Brain	(50)	(50)	(50)	(50)	
Compression	9	10	6		
Mineralization	1 [2.0]		1 [2.0]		
Pigmentation			2 [1.0]	4.50.03	
Pigmentation, Hemosiderin				1 [2.0]	
RESPIRATORY SYSTEM					
Lung	(50)	(50)	(50)	(50)	
Hemorrhage				1 [4.0]	
Hyperplasia		1 [2.0]			
Infiltration Cellular, Histiocyte	46 [1.0]	43 [1.0]	36 [1.1]	8 [1.0]	
Inflammation, Suppurative	40.54.53	1 [2.0]	5.14.03	4.54.03	
Inflammation, Chronic	10 [1.5]	3 [1.3]	5 [1.0]	1 [1.0]	
Metaplasia, Osseous Necrosis		1 [1.0]	2 [1.5]	1 [2 0]	
Alveolar Epithelium, Hyperplasia	23 [1.3]	25 [1.4]	17 [1.3]	1 [3.0] 4 [1.0]	
Nose	23 [1.3] (50)	25 [1. 4] (50)	(50)	4 [1.0] (50)	
Congestion	(50)	(30)	(50)	2 [2.5]	
Foreign Body	7 [1.3]	5 [2.0]	3 [1.3]	1 [1.0]	
Inflammation, Chronic	11 [1.5]	11 [1.8]	9 [1.4]	1 [1.0]	
Thrombosis	1	r -1			
Goblet Cell, Hyperplasia	1 [1.0]				
Nasolacrimal Duct, Cyst				1	

a - Number of animals examined microscopically at site and number of animals with lesion

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Species/Strain: RATS/F 344/N

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

alpha/beta Thujone mixture

CAS Number: THUJONEMIXAB

Time Report Requested: 08:41:38 First Dose M/F: 06/09/03 / 06/09/03

Date Report Requested: 05/28/2009

FISCHER 344 RATS FEMALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG	
Respiratory Epithelium, Hyperplasia	5 [1.0]	4 [2.3]	2 [1.5]		
SPECIAL SENSES SYSTEM					
Eye Cataract Edema	(44)	(47) 5 [2.2] 1 [2.0]	(41) 2 [3.0] 2 [2.5]	(49)	
Hemorrhage Inflammation, Acute	1 [3.0]	1 [4.0] 1 [2.0]	_ [=.0]		
Inflammation, Chronic Synechia Bilateral, Cataract	1 [2.0]	1 [1.0] 1 [3.0]	1 [2.0]		
Bilateral, Edema Bilateral, Retinal Detachment		1 [4.0] 1 [4.0]			
Retina, Degeneration Harderian Gland Hemorrhage	(50)	1 [3.0] (50)	2 [2.5] (49) 4 [2.0]	1 [2.0] (50)	
Hyperplasia Inflammation, Chronic	9 [1.0]	11 [1.2]	1 [3.0] 9 [1.3]	6 [1.5]	
JRINARY SYSTEM					
Kidney Casts Protein Cyst	(44) 14 [1.4] 1	(45) 8 [1.3] 1	(40) 12 [1.3]	(50)	
Infarct Inflammation, Suppurative	2 [2.5] 1 [2.0]	1 [4.0]	1 [4.0]		
Inflammation, Chronic Mineralization Nephropathy	16 [1.1] 33 [1.2]	1 [3.0] 24 [1.0] 36 [1.0]	3 [2.0] 17 [1.2] 26 [1.0]	8 [1.0] 4 [1.0]	
Renal Tubule, Accumulation, Hyaline Droplet	2 [2.0]	5 [2.0]	4 [2.8]	,	
Renal Tubule, Necrosis Transitional Epithelium, Hyperplasia Urinary Bladder	2 [2.0] (50)	1 [2.0] (50)	1 [1.0] (50)	(50)	
Inflammation, Chronic Transitional Epithelium, Hyperplasia	. ,	1 [2.0]	. ,	1 [1.0]	

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

TDMS No. 99037 - 05 Test Type: CHRONIC

Species/Strain: RATS/F 344/N

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH

AVERAGE SEVERITY GRADES[b] alpha/beta Thujone mixture

CAS Number: THUJONEMIXAB

Date Report Requested: 05/28/2009

Time Report Requested: 08:41:38 First Dose M/F: 06/09/03 / 06/09/03

Lab: SRI

ı	FISCHER 344 RATS FEMALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG

*** END OF REPORT ***

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)